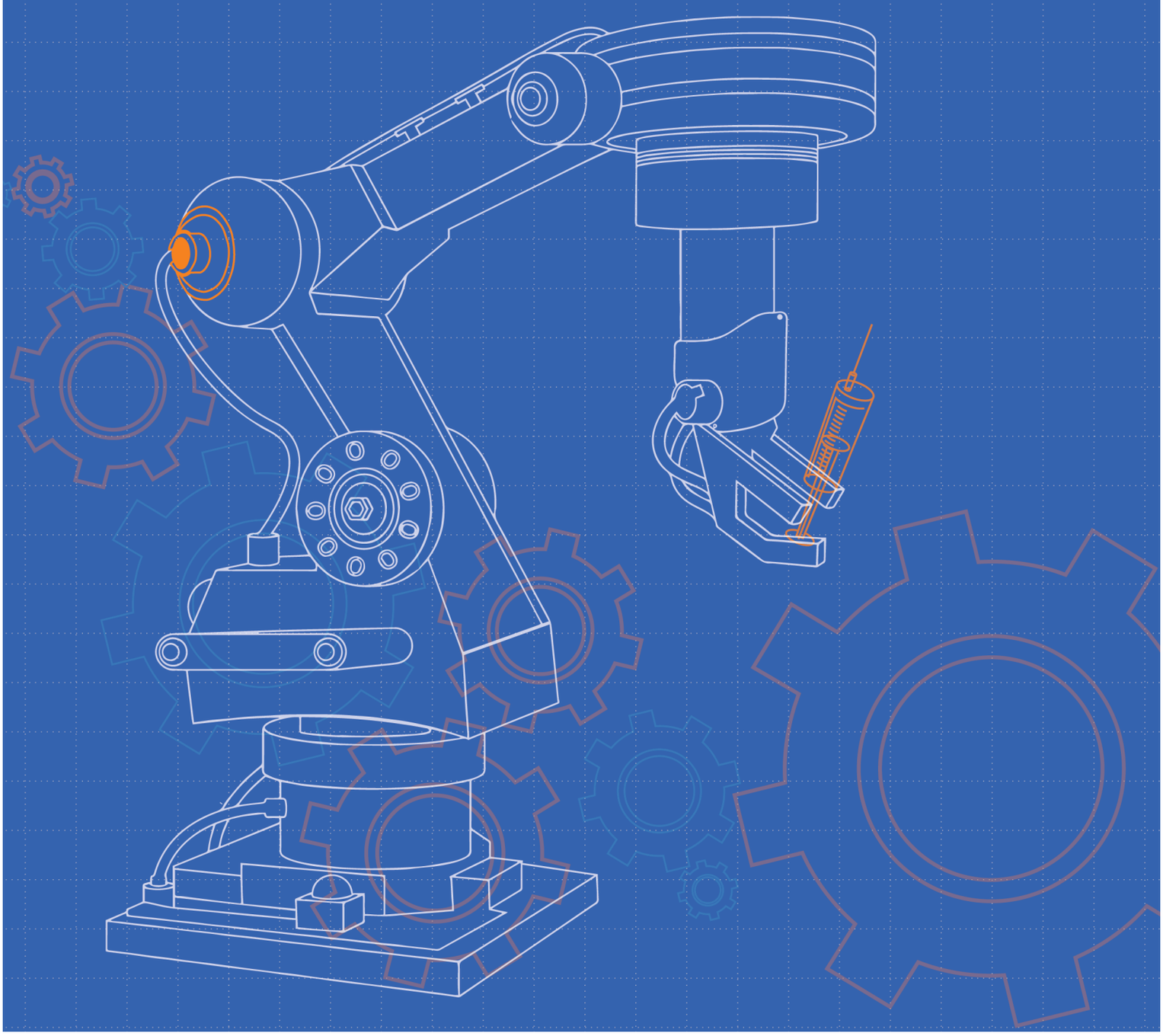
IZIEL HEALTHCARE

inspire : engineer : achieve



WHO WE ARE

IZiel is an ISO 9001:2015 certified organization built on the foundation of technical excellence, sound management practices and winning customer trust.

IZiel Healthcare provides Engineering, Software & Regulatory Services for global medical device companies from our offices in USA & India. IZiel has successfully completed projects in design, engineering documentation, process validation & improvement, software validation, cybersecurity, CER, regulatory approvals (USFDA, CE)/MDD-MDR Transition and remediation to resolve observations (Form 483) & warning letters.

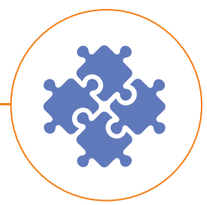
IZiel takes immense pride in our strong team comprising of talented engineers that have worked with large medical device manufacturers in USA, Europe and India.

IZiel's approach for an Outcome-Based Delivery along with the Cost-Effective Resource Model has worked very well for customers in USA, Europe and Asia. Our comprehensive evaluation and monitoring system ensure effective and timely deliveries.

OUR VALUES

INTEGRITY & TRUST

Build relationships within our team and with our clients.



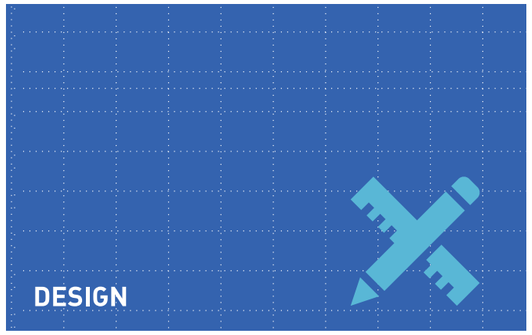
COMPETENCE

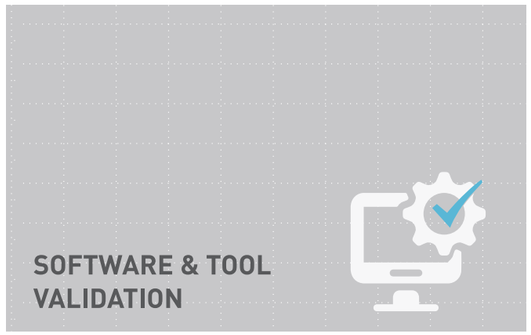
Build competent teams to deliver value added outcomes.

WALK THE EXTRA MILE

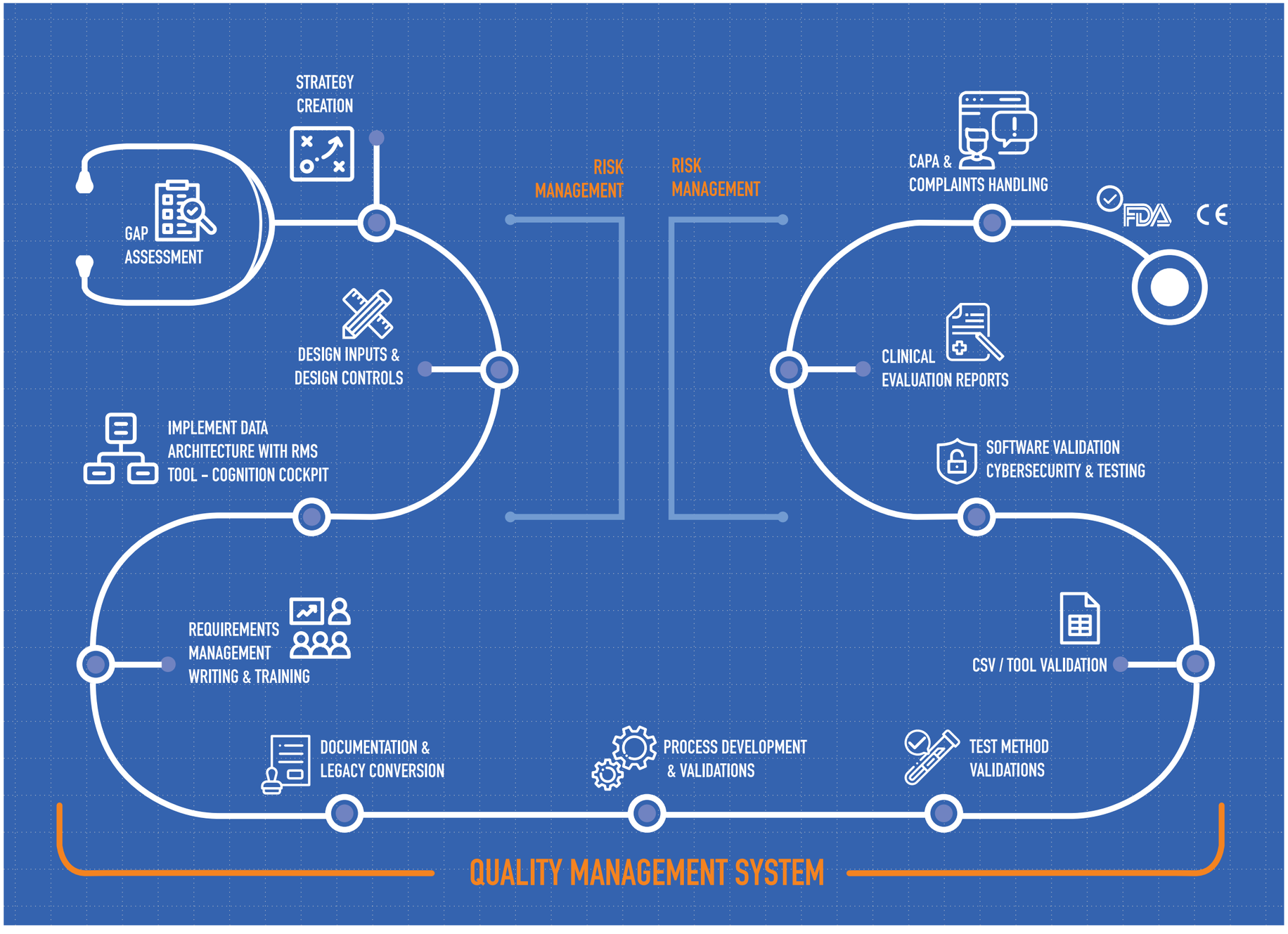
Be an equal partner with the client to achieve their goals.

OUR EXPERTISE





REMEDIATION / MDD - MDR



What is Remediation ?

- Observation (Form 483)
- Warning Letters from USFDA
- MDD - MDR Conversion
- Resolve product design & process development issues
- Substantial number of unplanned resources & budgets
- Declined opportunity to sell

Why IZiel Healthcare ?

- Expertise in medical device product development lifecycle
- Conduct a Methodical & Comprehensive Gap Assessment.
- Outcome Based Delivery Approach
- Partner with Remediation/MDR Experts
- Quick Scalability of Skilled Resources
  - Design
  - Process Engineering & Validation
  - Systems Engineering
  - Software Validation & Testing
  - QMS and Regulatory
- Assist in Complete Implementation
- Flexible Onshore/Offshore Model
- Significant Time and Cost Advantages
- Strong Project Management

ACQUISITION INTEGRATION

- Successful integration for one of the largest Class III medical device manufacturer.
- Team lead by experts with 20+ years experience with global medical device companies.
- Robust Post Acquisition Assessment
- Acquisition Risk Mitigation

  Resources | Implementation | Regulatory | Delay

2000+ Documents Completed

350+ DCO Approvals

30+ TMDs & TMVs Completed

15+ CAPAs

2500+ Labels Updated

200+ PCH & RCH Completed

35%

Cost & Time Advantages

Prioritize, Communicate & Execute Tasks Effectively

70%

Reduced Workload

Outcome Based Model with Complete Accountability & Ownership

100%

Customer Satisfaction

Best In Class Performance

Engineering Support

- Design Support – CAD, Cell Layout & Tools
- MPI Updates & Process Validation
- Labels Update - ISO 15223 & EU-MDR
- Product Commercialization

Risk Management

- Creation of User, Design & Process FMEA.
- Technical File Remediation
- Legacy Translation of Harms and Hazards
- Risk Management for transferred lines.

CAPA, Software & CSV

- CAPA Owners for Process Validation, PVP, Internal Audit NC, Operator Certification, Bacterial Endotoxin & Software Validation.
- Executed CSV for 25+ Softwares

Supplier Quality

- Identified Supplier Risk with PPK analysis of existing data
- FLQIA, PLQIA, CQD and Spec Updates.
- Support SCR and SCC activities

CE APPROVAL-MDR

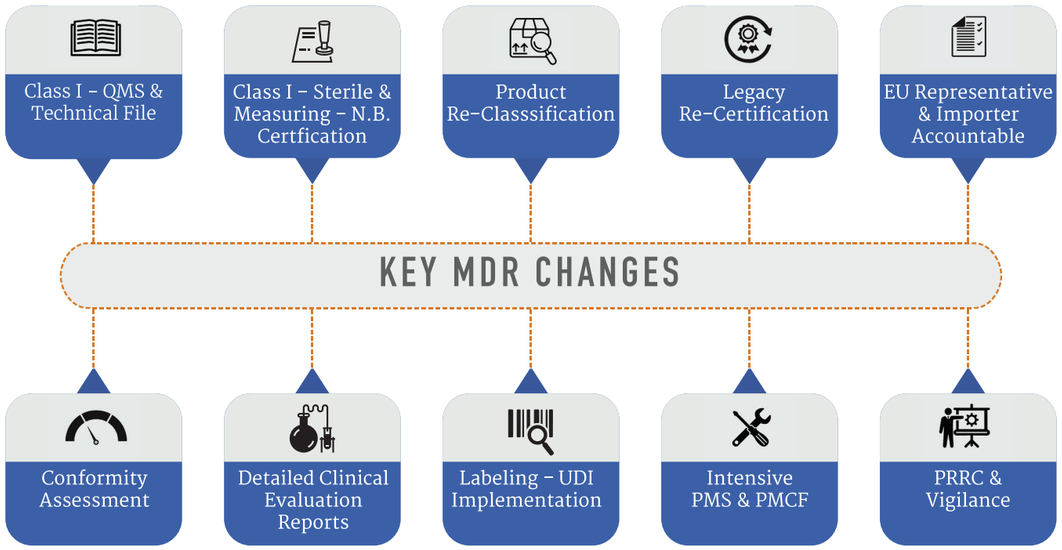
IZIEL - OBELIS Collaboration

Together, IZiel & Obelis formed a partnership to create a "One-Stop Shop" to fully support Class I, IIa, IIb, III medical device manufacturers across USA, Europe & Asia to obtain conformity with the MDR (2017/745) requirements and maintain their CE Marking - this, through technical support, consultancy, representation and device registration services.

Obelis is currently representing over 3000 exporters from more than 60 countries around the world.

ONE - STOP COMPLETE SOLUTION

- Gap Assessment
- QMS Documentation
- Technical File
- Software & Tool Validation
- CEP & CER
- Expert Review & Recommendations
- EUDAMED
- European Authorised Representative (EC REP)
- PRRC Services
- Mock Audits & Trainings



COMPETENCY & CASE STUDIES

CARDIO-VASCULAR | DIAGNOSTIC IMAGING | AI BASED DIAGNOSTICS | IN VITRO DIAGNOSTICS | DIABETOLOGY | DRUG DELIVERY | ORTHOPEDIC | DENTAL

- **MDD-MDR Transition**
  - Create MDR & FDA Compliant Design, Process, Software and Risk Management Documentation
  - Develop CEP & CER for Class I & II medical devices.
  - Support medical device manufacturers for Complaints Handling, PMS & Vigilance requirements.
- **Software Validation & Computer System Validation**
  - Develop Technical File for Medical devices, AI based & wearables compliant to IEC 62304 & 82304
  - Software CAPA owners for leading medical device companies.
  - Resolve FDA queries & remediate several Class II SaMD devices.
- **Acquisition Integration**
  - Successful Integration for one the largest Class III medical device manufacturer.
  - Completed Post Acquisition Assessment, Process Validation, Risk Management, CSV, Supplier Quality and CAPA projects.
  - Project Management using higly efficient Onshore-Offshore Model.
  - Significant Cost and Time Savings with Complete Customer Satisfaction.
- **USFDA Approval & Regulatory Strategy for Diagnostic Imaging Equipment**
  - IZiel Hybrid Model bringing in cultural change to complete Design History File (DHF).
  - Received USFDA Approval for X Ray Equipment within 1 month.
- **Product Design & Development for Myonic Arm**
  - Project Approved and Funded by BIRAC, Government of India.
  - Product Design, Modeling & Detailing for 5 gestures covering 80% of hand movement.
- **Productivity Improvement for Disposable Products of a large German Manufacturer**
  - Adopt DFSS & Lean Manufacturing Principles along with Process Automation.
  - Productivity increased by 25% occupying only 70% of the existing space.

ACHIEVEMENTS

'Top 20 MedTech Solution Providers in APAC - 2018.'

-MedTech Outlook magazine

Key Sponsor & Presenter

- American Medical Device Summit in USA -2022

- Software Development Summit in USA – 2021, 2022

Empanelled with Andhra Pradesh MedTech Zone, Government of India

'25 fastest growing MedTech companies in India, 2017'

-CEO magazine

CLIENTS

Work done for 70+ global medical device companies through IZiel Healthcare.

- Medtronic
- Epicor
- Helen of Troy
- Magic Leap
- Erbe Vision
- Air Liquide
- Nitto Denko
- Becton Dickinson
- Zest Dental
- PBS Biotech
- Cantel
- Mediso Imaging
- Medicor
- USM Healthcare
- Harvard Biosciences
- Hiossen
- Amsino
- Remidio Innovations
- Cair LGL
- Agappe
- Hospitech
- Coloplast
- Invoy
- Spacelabs
- Primus Sterilizer
- Sterisys
- Skanray
- Alveofit

COLLABORATIONS & PARTNERSHIPS

IZiel Healthcare has developed a strong global presence by developing collaborations and partnerships to help medical device companies with -

- Functional Teams in USA, Germany & India
- Quick Scalability for Faster Timelines
- Lower Budgets / Costs
- Strategy & Implementation with strong Project Management
- Short Term Deployment with quick turnaround

SELEON (GERMANY) –

- Engineering Documentation, New Product Development, MDD-MDR, Software Validation & Regulatory Services
- Combined Teams in Europe, USA & India for robust deliverables within time & budget

EPICOR (USA) –

- Tool Validation for EPICOR ERP Software used in medical device industry
- CSV of appropriate ERP modules as per GAMP 5 and CFR 820.70 guidelines

OBELIS (BELGIUM) –

- MDD - MDR Transition for Class I, IIa, IIb & III medical devices
- EC / UK Representative along with expert review for documentation

COGNITION CORPORATION (USA) –

- Sole Reseller of QMS & Requirements Management Software in Asian Region
- Software Customization, Data Migration and Implementation of Cognition Cockpit

REGULATORY CONSULTANTS (USA) –

- Regulatory Partners for 510(k) / PMA Submissions for USFDA Approval
- Ex-FDA Auditors with more than 3500+ reviews and approvals

SPELLBOUND INC. (INDIA) –

- Preparation of Clinical Evaluation Plans & Reports
- 30+ National Board Certified Physicians

MANUFACTURING & MARKETING

- Joint Venture, Collaboration for manufacturing and marketing unique medical devices in Asia
- Industrial Infrastructure - 20,000 sq.ft. building 1,00,000 sq. ft. for future expansions
- Strong engineering, regulatory and sales team along with distributor network
- Product registration support

INTEGRIMEDICAL

NEEDLE FREE DRUG DELIVERY

- Needle-Phobia
- Non Invasive
- Broad Dispersion
- Effective Absorbtion

Intramuscular (IM) | Subcutaneous (SC)

IZIEL HEALTHCARE

inspire : engineer : achieve

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